ITCW

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of : Francis T. GILES et al.

Serial No.: 10/729,387 Group Art Unit: 1614

Filed: December 8, 2003 Examiner: Unassigned

For: PHARMACEUTICAL COMBINATIONS AND METHODS FOR THE TREATMENT OF LEUKEMIA

INFORMATION DISCLOSURE STATEMENT UNDER 37 CFR §§ 1.56, 1.97 and 1.98

MAIL STOP AMENDMENT
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

This information disclosure statement is made in accordance with 37 C.F.R. §§ 1.56, 1.97 and 1.98 as follows:

Timing and Fees

☒ Under 37 C.F.R. § 1.97(b), no fee or statement is required for filing this information disclosure statement is filed:

- ☐ within three months of the filing date of a national application other than a CPA under § 1.53(d);
- ☐ within three months of the actual filing date of the national phase of a PCT application; OR
- ☒ before the mailing of a first substantive office action (including after filing of an RCE).

☐ Under 37 C.F.R. § 1.97(c), this information disclosure statement is filed after the periods specified in 37 C.F.R. § 1.97(b), but before the mailing date of:

- ☐ a final rejection under 37 C.F.R. 1.113;
- ☐ termination of prosecution, e.g. Ex Parte Quayle, M.P.E.P § 609(B)(2); OR
- ☐ a notice of allowance under 37 C.F.R. § 1.311; and

is accompanied by:

☐ the statement as specified in 37 C.F.R. § 1.97(e) set out below; OR

☐ a check covering the fee of $180.00 under 37 C.F.R. § 1.17(p).

☐ Under 37 C.F.R. § 1.97(d), this information disclosure statement is filed after the mailing date of the following actions which have not been withdrawn:

☐ a final action under 37 C.F.R. § 1.113;

☐ termination of prosecution, e.g. Ex Parte Quayle, M.P.E.P § 609(B)(2); OR

☐ a notice of allowance under 37 C.F.R. § 1.311;

AND is filed on or before payment of the issue fee; AND is accompanied by:

☐ the statement as specified in 37 C.F.R. § 1.97(e) as set forth below, and the fee of $180.00 under 37 C.F.R. § 1.17(p).

Statements Under 37 C.F.R. 1.97(e)

☐ Each item of information contained in this information disclosure statement was a first cited in a communication from a foreign patent office in a counterpart foreign application having a mailing date not more than three months prior to the filing date of this information disclosure statement; or

☐ No item of information contained in this information disclosure statement was cited in a communication from a foreign patent office in a counterpart foreign application, and to the knowledge of the undersigned attorney after making reasonable inquiry, no item of information contained in this information disclosure statement was known to any individual designated in 37 C.F.R. § 1.56(c) more than three months prior to the filing date of the information disclosure statement.

Cited Materials

☐ Copies of materials listed but not attached were cited in benefit (35 U.S.C. § 120) ancestor application Serial No. _____, on Form 892 by the Examiner and/or Form 1449 by the applicant; see 37 C.F.R. § 1.98(d).

☐ Copies of materials listed were cited in an international search report dated _____.

☒ Copies of the materials listed are attached (except for the foregoing).

Non-English Language References

☐ An English-language search report or equivalent paper from a foreign patent office is provided indicating the relevance of the cited reference(s).

☐ A foreign-language search report from a foreign patent office is provided, and pertinent parts are translated substantively below:

X = document of particular relevance when it is taken alone
Y = document of particular relevance when it is combined with another such document
A = document defining the general state of the art
O = non-written disclosure
P = intercalated document
T = document cited to understand the theory or principle underlying the invention
E = patent document which has the benefit of a date earlier than the filing date and which was published only on or after this filing date
D = cited in the application
L = cited for another reason
& = publication of member of same patent family

☐ Translation of other relevant information on foreign search report

☒ Other Information

The instant application is related to US patent applications Serial Nos. 09/976,249, 10/104,067, 10/107,795, 10/824,563, and 10/853,241. The Published Applications corresponding to 09/976,249, 10/104,067, 10/107,795, and 10/824,563 are listed on the attached PTO-1449. Serial No. 10/853,241 is a divisional of 10/104,067.

Payment of Fees Due (If Any):

☐ A check for $_____ covering the fee identified above is attached.

☐ Please charge to Deposit Account No. 13-3402 $_____ for the fee identified above.

☒ The Commissioner is hereby authorized to charge or credit any overpayment to Deposit Account #13-3402, two copies of this paper are attached for this purpose.

Respectfully submitted,

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Attorney Docket No. STORMIX-7

Date: October 27, 2004

BPH/rrt

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Substitute for form 1449A/PTO

INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(use as many sheets as necessary)

Sheet 1 of 2

Complete if Known	
Application Number	10/729,387
Filing Date	December 3, 2003
First Named Inventor	Francis T. GILES
Group Art Unit	1614
Examiner Name	Unassigned
Attorney Docket Number	STROMIX-007

U.S. PATENT DOCUMENTS

Examiner Initials *	Cite No.[1]	U.S. Patent Document Number	Kind Code[2] (*if known*)	Name of Patentee or Applicant of Cited Document	Date of Publication of Cited Document MM-DD-YYYY	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
		5,041,449		Belleau et al	08/20/1991	
		5,817,667		Chu et al	10/06/1998	
		5,270,315		Belleau et al	12/14/1993	
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		6,747,036		Gordeau et al.	6/8/2004	
		2003/0013660		Attardo et al.	1/16/2003	
		2003/0083316		Giles et al.	5/1/2003	
		2003/0027799		Jolivet	2/6/2003	
		2004/0192654		Gourdeau et al.	9/30/2004	

FOREIGN PATENT DOCUMENTS

Examiner Initials*	Cite No.[1]	Foreign Patent Document Office[3]	Number[4]	Kind Code[5] (*if known*)	Name of Patentee or Applicant of Cited Document	Date of Publication of Cited Document MM-DD-YYYY	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	T_6
		WO	9607413			03/14/1996		
		EP	0337713			10/18/1995		
		WO	02/30922			04/18/2002		
		WO	02/076472			10/03/2002		
		WO	02/078678			10/10/2002		
		WO	03/037344			5/8/2003		

Examiner Signature		Date Considered	

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

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INFORMATION DISCLOSURE STATEMENT BY APPLICANT

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Sheet 2 of 2

Complete if Known	
Application Number	10/729,387
Filing Date	December 3, 2003
First Named Inventor	Francis T. GILES
Group Art Unit	1614
Examiner Name	Unassigned
Attorney Docket Number	STROMIX-0007

OTHER PRIOR ART -- NON PATENT LITERATURE DOCUMENTS

Examiner Initials *	Cite No.[1]	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T[2]
		"FDA Approves Gleevec for Leukemia Treatment" FDA Consumer, US Dept. of Health, Educ. And Welfare, Public Health Services, US, vol. 4, July 2001, pg. 6, XP001145627	
		Giles F. et al. "Phase II Study of Troxatyl in Patients with Chronic Myeloid Leukemia in Blastic Phase (CML-BP)" Blood, W.B. Saunders Company, Orlando, FL, US, vol. 98, no. 11, part 2, (2001), pg. 258B, XP009007253	
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		M. Beran et al, "Biological properties and growth in SCID mice of a new myelogenous leukemia cell line (KBM-5) derived from chronic myelogenous leukemia cells in the blastic phase", Cancer Res. 1993 Aug 1;53(15):3603-10	
		B. Kasper et al, "Favorable therapeutic index of a p210 BCR-ABL specific tyrosine kinase inhibitor; activity on lineage-committed and primitive chronic myelogenous leukaemia progenitors", Cancer Chemother Pharmacol (1999) 44:433-438	
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		"Gleevec (STI-571) for chronic myeloid leukemia", Medical Letter on Drugs and Therapeutics, New Rochelle, NY, US, June 11, 2001, Vol. 43, No. 1106, pp. 49-50, XP001036570	
		M. Kotecki et al, "Isolation and characterization of a near-haploid human cell line", Exp Cell Res. 1999 Nov 1;252(2):273-80	
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		J. Toplay et al, "Synergistic activity of the new ABL-specific tyrosine kinase inhibitor ST1571 and chemotherapeutic drugs on BCR-ABL-positive chronic myelogenous leukemia cells", Leukemia (2001) 15;342-347	

Examiner Signature		Date Considered	

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